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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,919	06/14/2002	Michael Panaccio	DAVI151.001APC	1078

7590 05/20/2004

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,919	PANACCIO ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,10,11,13,14 and 17-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4, 6-8, 10-11, 13-14 and 17-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESTRICTION

Amendments

1. Applicant's preliminary amendment and supplemental amendments filed on 3/11/01 and 3/19/02 have been entered.

Status of Claims

2. Claims 5, 9, 12, 15 and 16 have been canceled.

Claim 24 has been amended.

Claims 1-4, 6-8, 10-11, 13-14 and 17-48 are pending in the application.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 6-8, 10, 11, 13, 14 and 17-26 drawn to an isolated or recombinant immunogenic polypeptide comprising the Lawsonia hemolysin polypeptide, variant or truncated variant thereof, a vaccine composition comprising SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK12 (see Para # 5)

Group II, claims 28 –30, 37-42, 46 and 47 drawn to a vaccine vector, polynucleotide that encodes the immunogenic polypeptide SEQ.ID.NO: 1 or polynucleotide , SEQ.ID.NO: 2 or Plasmid pALK 12 or Plasmid pALK 13 (see Para # 5)..

Group III, claims 31-33 drawn to antibody that binds to SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK12 (see Para # 5).

Group IV, claims 27 and 48 drawn to a combination vaccine composition comprising the first component comprising the amino acid sequence set forth in SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK12 and a second immunogenic component comprising OmpH, FigE, hemolysin and autolysin. (see Para # 5).

Group V, Claims 34-35 drawn to a method for diagnosing the infection of L.intracellularis using antibody that binds to SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK12 (see Para # 5).

Group VI, claim 36 drawn to a method of identifying a previous infection or current infection Lawsonia intracellularis using an immunogenic polypeptide, SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK12 (see Para # 5).

Group VII claims 43-45 drawn to a method for identifying Lawsonia intracellularis in a sample using DNA polynucleotide that encodes the immunogenic polypeptide SEQ.ID.NO: 1 or polynucleotide, SEQ.ID.NO: 2 or Plasmid pALK 12 or Plasmid pALK 13. (see Para # 5).

4.The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special feature technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to peptides, nucleic acids and antibodies and methods using said peptides, nucleic acids and antibodies. The technical feature of linking groups appears to be that they are all related to peptides, nucleic acids and antibodies and methods using said peptides, nucleic acids and antibodies. However, Panaccio W0 97/0050 discloses an isolated polypeptide or recombinant polypeptide comprising Lawsonia variant (see claims) and thus read on the variants of claimed invention. Various proteins recognized by western blots read on variant that mimics T-cell or B-cell

epitopes of Lawsonia. These proteins were reacted to antibodies obtained from vaccinated sera (see example 14) indicating that these are immunogenic polypeptides. Therefore, no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Therefore, it does not constitute a special technical feature by definition and hence unity of invention is lacking.

Therefore, the technical feature of linking groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

The special technical feature of Group I is considered to be polypeptide, which is made up of amino acids.

The special technical feature of Group II is considered to be polynucleotide that shares no common structure, property and function with Group I since peptides contain amino acids and do not share the same or a corresponding technical feature with Group II, DNA.

The special technical feature of Group III considered to be antibody that shares no common structure, property and function from Inventions I-II since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing and do not require each other for their practice.

Since the special technical feature of the Group I invention is not present in the Group II-III claims, and the special technical features of the Group II-III inventions are not present in the Group I claims, unity of invention is lacking.

The technical feature linking Groups IV-VII is considered to be combination vaccine comprising more than one recombinant peptide in group IV that share no common structure with group I as it contains various components and methods groups V-VII utilizing products that share no common structure, property and function and methods of using products so as to

form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups IV-VII.

Accordingly, Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

DISTINCT INVENTIONS

5. For each group of inventions I-VII above, restriction to one of the following is also required under 35 U.S.C. 121 and 372 as it is not clear that the nucleotide sequence pALK12 has more than one coding sequence and encodes more than one polypeptide.

The election is required to one of the groups I-VII and one of the inventions from SEQ ID NO: 1 , the amino acid sequence encoded by the nucleotide sequence pALK12, plasmid pALK12 , plasmid pALK13 , and SEQ.ID.NO: 2 .

Inventions SEQ ID NO: 1, the amino acid sequence encoded by the nucleotide sequence pALK12, plasmid pALK12, plasmid pALK13 and SEQ.ID.NO: 2 are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed peptides SEQ ID NO: 1or the amino acid sequence encoded by the nucleotide sequence pALK12, plasmid pALK12, plasmid pALK13 and nucleic acid molecules SEQ.ID.NO: 2 share no common special technical feature because the peptides and nucleic acid molecules have no common structure (i.e., no common sequence), property and function.

Peptide SEQ ID NO: 1, the amino acid sequence encoded by the nucleotide sequence pALK12, plasmid pALK12 , plasmid pALK13 and nucleic acid molecules SEQ.ID.NO: 2 represent sequences that share no common structure as polypeptides and the polynucleotides encoding them are not linked by the same the same or a corresponding special technical

feature as to form a single general inventive concept. Therefore, where structural identity is required, such as for hybridization or expression of protein or binding of antibody, each sequence appears perform a different function in that peptides elicit an antibody response and nucleic acids encode peptides that specifically bind to an antibody. Thus they share no common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups SEQ.ID.NOS.

Applicant is required under Restriction is required under 35 U.S.C. 121 and 372 to elect a single disclosed Invention from SEQ ID NO: 1, one amino acid sequence encoded by the nucleotide sequence pALK12, one sequence from plasmid pALK12, plasmid pALK13 and SEQ.ID.NO: 2 from any group elected.

Applicant is advised to point to the examiner if SEQ ID NO: 1 and the amino acid sequence encoded by the nucleotide sequence pALK12 are same. Similarly, applicant is advised to clarify the polynucleotide sequence from plasmid pALK12 , plasmid pALK13 and the polynucleotide sequence SEQ.ID.NO: 2 are the same sequences or different because the claims are not clear on the record. The examiner is considering that the plasmid contains more than nucleic acid sequence. Therefore, clarification is required.

If applicant elects group IV, then applicant should elect one first immunogenic component as stated above and in addition one second immunogenic component from OmpH, FigE, hemolysin and autolysin.

6. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

7. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

8 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

5/10/04

L. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER